OSTI-LBNL QUALITY ASSURANCE PLAN

1.0 INTRODUCTION

The U.S. Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM) Office of Science and Technology and International (OSTI) has determined a need for developmental, exploratory studies to support the licensing of a high-level nuclear waste repository at Yucca Mountain, Nevada. To meet the needs of the repository, OSTI has funded initial proposals from various areas of scientific and technical expertise that are considered beyond the baseline scientific activities being conducted by the OCRWM Yucca Mountain Project (YMP).

The work to be performed within the Lawrence Berkeley National Laboratory (LBNL) Nuclear Waste Program (NWP), hereafter referred to as the OSTI-LBNL Project, is a multi-year, multi-divisional project that includes, but is not limited to scientific analysis, modeling, and testing activities. All OSTI-LBNL work designated as quality-related (Q) by OCRWM will be conducted in accordance with the quality assurance (QA) requirements outlined in this OSTI-LBNL QA Plan.

2.0 SCOPE

The OSTI-LBNL QA Program developed for the OSTI-LBNL Project consists of this QA Plan, OSTI-LBNL Quality Implementing Procedures (QIPs), and OSTI-LBNL Technical Implementing Procedures (TIPs). The OSTI-LBNL QA Program satisfies the requirements of the DOE OCRWM *Quality Assurance Requirements and Description* (QARD), DOE/RW-0333P, developed for the YMP, where applicable.

Table QAP-1 presents a matrix that summarizes the QARD requirements imposed on the OSTI-LBNL QA Program for OSTI-LBNL Q work. Each Section briefly identifies the QARD requirements for that Section, provides LBNL supplementary comments, clarifications, exceptions, justifications thereof, and identifies the OSTI-LBNL QA Program documents that will implement these requirements.

Table QAP-1

QARD Basic Requirements	Comments/Clarification, Exceptions/Justification	OSTI-LBNL QA Program Implementing Documents (current version)
Section 1.0, ORGANIZATION One or more controlled documents, accepted by the OCRWM Office of Quality Assurance (OQA) shall be prepared that describes the responsibilities and authorities, including management positions responsible for achieving and maintaining quality, internal and external organizational interfaces, organizational structures, requirements, and responsibilities for assigned scope of work. Quality shall be achieved and maintained by those staff assigned responsibility for performing the work. The achievement of quality shall be verified by persons or organizations not directly responsible for performing the work. Differences of opinion involving QA program requirements shall be brought to the attention of appropriate management and, if not resolved, shall be elevated progressively to successively higher levels of management.	The OSTI-LBNL QA Program has been written to address QA requirements applicable to LBNL. Certain QA functions performed by the OCRWM/ OQA (i.e., audits, qualification of suppliers) as mutually agreed upon between OQA and LBNL will be credited as satisfying the OSTI-LBNL-QA Program requirements as noted within this plan. The OSTI-LBNL QA Manager shall retain responsibility for all QA functions and request services to be performed by OCRWM/OQA, as needed.	OSTI-LBNL-QIP-1.0, *OSTI-LBNL Organizational Structure* OSTI-LBNL-QIP-6.1, *Document Review* OSTI-LBNL-QIP-15.0, *Nonconformances* OSTI-LBNL-QIP-16.0, *Condition Reporting and Resolution*
Section 2.0, QUALITY ASSURANCE PROGRAM A policy statement signed by senior line management shall be issued directing mandatory compliance with this QA Program. Implementing documents shall be established that are applicable to the scope of work that translate QARD requirements into work processes. Revisions to the QARD shall be reviewed and changes incorporated to implementing documents as appropriate. A QARD requirements matrix shall be completed for the portion of the QARD that are applicable. The program shall be applied to Q activities under the scope of OCRWM contracts. Planning shall be documented to ensure work is accomplished under suitably controlled conditions. Surveillances shall be conducted to evaluate the quality of work in progress. Surveillances shall be performed by persons knowledgeable, but not directly responsible, for the work under surveillance.	The OSTI-LBNL QA Program has been written to address QA requirements applicable to LBNL. Work is classified as "Q" or "Non-Q" by DOE within Guidance and Funds memoranda. Work classified as "Q" shall comply with all applicable OSTI-LBNL QA Program requirements. Surveillances shall be performed by OSTI-LBNL to internally evaluate	*OSTI-LBNL QA Policy Statement* *OSTI-LBNL Quality Assurance Plan* OSTI-LBNL-QIP-2.0, *Indoctrination and Training of Personnel* OSTI-LBNL-QIP-2.1, *Establishment and Verification of Required Education and Experience of Personnel* OSTI-LBNL-QIP-2.2, *Planning for Science Activities* OSTI-LBNL-QIP-2.3, *Surveillances*

QARD Basic Requirements	Comments/Clarification, Exceptions/Justification	OSTI-LBNL QA Program Implementing Documents (current version)
Management assessments of the Organization by personnel outside the QA organization shall be planned, documented, and performed annually. The need for readiness reviews and peer reviews shall be identified by management for major scheduled or planned work. Implementing documents and documents that specify technical or quality requirements shall be reviewed by qualified individuals other than the preparer. The QA organization shall review implementing documents and changes thereto that translate the QARD into work processes. Management shall on a continuing basis be apprised of the status, adequacy and compliance aspects of the QA Program. Appropriate indoctrination and training shall be determined to ensure personnel are indoctrinated and trained, as needed to achieve initial proficiency, maintain proficiency, and to adapt to changes in technology, methods, or job responsibilities; the need for additional indoctrination and training shall be evaluated, assessed, and performed as assignments, positions, or implementing documents change. Personnel shall have the experience and education commensurate with the minimum requirements established.	compliance with the OSTI-LBNL QA Program. Management assessments may be conducted by an independent organization, as appropriate. Assistance in performing management assessments of the OSTI-LBNL organizations and activities may be requested from OCRWM, as needed. Thus far, readiness reviews or peer reviews have not been scheduled to be performed on the OSTI-LBNL Project	OSTI-LBNL-QIP-5.0, *Preparing the Quality Assurance Plan and Quality/Technical Implementing Procedures* OSTI-LBNL-QIP-6.1, *Document Review* OSTI-LBNL-QIP-18.0, *Quality Assurance Audits and Management Assessments* OSTI-LBNL-QIP-SI.0, *Software Management* OSTI-LBNL-QIP-SIII.0, *Scientific Notebooks* OSTI-LBNL-QIP-SIII.4, *Qualification of Unqualified Data* Procedures will be developed as the need for a Readiness Review or Peer Review is determined.
Section 3.0, DESIGN CONTROL Applicable design inputs (such as design bases, conceptual design reports, performance requirements, regulatory requirements, codes, and standards) shall be controlled by those responsible for the design.	Not applicable to current OSTI-LBNL tasks.	N/A
Section 4.0, PROCUREMENT DOCUMENT CONTROL Technical and quality requirements shall be incorporated into procurement documents. The documents must include a reference to the supplier QA program /procedure accepted by OCRWM. The right of access to the suppliers' facilities by the Organization and/or DOE is to be included in the procurement document. Documentation to be furnished by the supplier shall be specified.	The OSTI-LBNL QA Program has been written to address QA requirements applicable to LBNL.	OSTI-LBNL-QIP-4.0, *Procurement Document Control* OSTI-LBNL-QIP-12.0, *Control of Measuring and Test Equipment and Calibration Standards*

QARD Basic Requirements	Comments/Clarification, Exceptions/Justification	OSTI-LBNL QA Program Implementing Documents (current version)
Section 5.0, IMPLEMENTING DOCUMENTS Activities shall be performed in accordance with approved implementing documents. The documents shall describe the work/activity to be performed, the responsibilities and organizational interfaces affected by the document, technical and QA requirements, sequential description of the work to be performed, acceptance criteria, prerequisites, quality verification hold points, methods for demonstrating that the work was performed as required, and required records. An individual technically competent in the subject area shall review the documents, and the review shall be performed by someone other than the preparer of the document. These documents shall include or reference quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished.	The OSTI-LBNL QA Program has been written to address QA requirements applicable to LBNL.	OSTI-LBNL-QIP-2.2, *Planning for Science Activities* OSTI-LBNL-QIP-5.0, *Preparing the Quality Assurance Plan and Quality/ Technical Implementing Procedures* OSTI-LBNL-QIP-6.1, *Document Review* OSTI-LBNL-QIP-SIII.0, *Scientific Notebooks*
Section 6.0, DOCUMENT CONTROL The preparation, issue, review, approval, change, and control of documents that specify quality requirements or prescribe activities affecting quality shall be controlled.	The OSTI-LBNL QA Program has been written to address QA requirements applicable to LBNL.	OSTI-LBNL-QIP-5.0, *Preparing the Quality Assurance Plan and Quality/Technical Implementing Procedures* OSTI-LBNL-QIP-6.0, *Controlled Documents* OSTI-LBNL-QIP-6.1, *Document Review*
Section 7.0, CONTROL OF PURCHASED ITEMS AND SERVICES The procurement of items and services shall be controlled to assure conformance with specified requirements. Supplier selection shall be based on an evaluation, performed before the contract is awarded, of the supplier's capability to provide items or services in accordance with procurement document requirements.	The OSTI-LBNL QA Program has been written to address QA requirements applicable to LBNL. It is intended that OSTI-LBNL quality-affecting procurement sources are limited to those on the OCRWM approved Qualified Supplier List (QSL). However, should a supplier be needed that is not on the QSL, OSTI-LBNL will request the OCRWM/OQA to provide source audits for	OSTI-LBNL-QIP-7.0, *Control of Purchased Services*

QARD Basic Requirements	Comments/Clarification, Exceptions/Justification	OSTI-LBNL QA Program Implementing Documents (current version)
	the purpose of placing the potential supplier on the OCRWM QSL.	
Section 8.0, IDENTIFICATION AND CONTROL OF ITEMS Controls shall be established to assure that only correct and accepted items/specimens are used or installed. Identification shall be maintained on the items/specimens or in documents traceable to the items, or in a manner that assures that identification is established and maintained.	Not applicable to current OSTI-LBNL tasks.	N/A
Section 9.0, CONTROL OF SPECIAL PROCESSES Special processes affecting quality of items or services shall be controlled. Special processes that control or verify quality, such as those used in welding, heat-treating, etc., shall use qualified personnel using qualified procedures in accordance with specified requirements.	Not applicable to current OSTI-LBNL tasks.	N/A
Section 10.0, INSPECTION Inspections required that verify conformance of an item or activity to specified requirements shall be planned and executed. Characteristics to be inspected and inspection methods to be employed shall be specified. Inspection results shall be documented. Qualified personnel other than those who performed or directly supervised the work being inspected shall perform inspections.	Not applicable to current OSTI-LBNL tasks.	N/A
Section 11.0, TEST CONTROL Tests verifying conformance of an item or activity to specified technical requirements shall be planned and executed. Characteristics to be tested and test methods to be employed shall be specified. Test results shall be documented and their conformance with acceptance criteria shall be determined. Tests to collect data shall be planned, executed, documented, and evaluated.	Not applicable to current OSTI-LBNL tasks.	N/A

QARD Basic Requirements	Comments/Clarification, Exceptions/Justification	OSTI-LBNL QA Program Implementing Documents (current version)
Section 12.0, CONTROL OF MEASURING AND TEST EQUIPMENT Measuring and test equipment (M&TE) shall be controlled, calibrated and maintained. The method and interval of calibration for each device shall be defined based on the type of equipment, intended use, required accuracy and other conditions affecting measurement control. Calibrated M&TE shall be uniquely identified to provide traceability to its calibration data and to nationally recognized standards.	The OSTI-LBNL QA Program has been written to address QA requirements applicable to LBNL.	OSTI-LBNL-QIP-12.0, *Control of Measuring and Test Equipment and Calibration Standards* OSTI-LBNL-QIP-15.0, *Nonconformances*
Section 13.0, HANDLING, STORAGE AND SHIPPING Handling storage, cleaning, packaging, shipping, and preservation of items shall be controlled to prevent damage or loss and to minimize deterioration.	Not applicable to current OSTI-LBNL tasks.	N/A
Section 14.0, INSPECTION, TEST & OPERATING STATUS The status of inspection and test activities shall be identified either on the items or in documents traceable to the items where it is necessary to assure that required inspections and tests are performed and to assure that items which have not passed the required inspections and tests are not inadvertently installed, used or operated.	Not applicable to current OSTI-LBNL tasks.	N/A
Section 15.0, NONCONFORMANCES Items that do not conform to specified requirements shall be controlled to prevent inadvertent installation or use. Controls shall provide for identification, documentation, evaluation, and segregation when practical, disposition of nonconforming items, and evaluation for quality trends.	The OSTI-LBNL QA Program has been written to address QA requirements applicable to LBNL.	OSTI-LBNL-QIP-12.0, Control *of Measuring and Test Equipment and Calibration Standards* OSTI-LBNL-QIP-15.0, *Nonconformances*
Section 16.0, CORRECTIVE ACTION A control system for identifying and documenting deviations from technical and quality implementing documents shall be established. Conditions adverse to quality shall be classified in regard to their significance and corrective actions shall be taken accordingly. Adverse conditions shall be reported to appropriate	The OSTI-LBNL QA Program has been written to address QA requirements applicable to LBNL.	OSTI-LBNL-QIP-2.3, *Surveillances* OSTI-LBNL-QIP-15.0, *Nonconformances* OSTI-LBNL-QIP-16.0, *Condition Reporting and Resolution*

QARD Basic Requirements	Comments/Clarification, Exceptions/Justification	OSTI-LBNL QA Program Implementing Documents (current version)
management responsible for the condition that shall determine the extent of the condition and take corrective actions as soon as practical. Process shall be established to verify the implementation of corrective actions prior to closeout of the documentation associated with the conditions adverse to quality. Nonconformances and conditions adverse to quality shall be analyzed for quality trends and root causes.		OSTI-LBNL-QIP-18.0, *Quality Assurance Audits and Management Assessments*
Section 17.0, RECORDS QA records shall be classified as lifetime or nonpermanent. Implementing documents are to specify what documents are to be considered quality records. Methods shall be established for specifying, preparing, and maintaining records that provide evidence of quality. The preparation, protection, storage, retention period and turnover of records shall be controlled.	The OSTI-LBNL QA Program has been written to address QA requirements applicable to LBNL.	OSTI-LBNL-QIP-5.0, *Preparing the Quality Assurance Plan and Quality/Technical Implementing Procedures* OSTI-LBNL-QIP-6.0, *Document Control* OSTI-LBNL-QIP-17.0, Records *Management*
Section 18.0, AUDITS Planned and scheduled internal audits shall be performed annually of those elements of the QA Program that address the quality requirements described in the procurement documents. The purpose of these audits is to verify compliance with the QA program requirements and to determine effectiveness of implementation of the QA program. Planned and scheduled internal audits shall be performed at a frequency commensurate with the status and importance of the work.	The OSTI-LBNL QA Program has been written to address QA requirements applicable to LBNL. Audits of OSTI-LBNL Project activities will be requested by the OSTI-LBNL QA Manager to be performed by OCRWM/OQA annually, or as needed. Should LBNL require the use of a supplier not on the QSL, the OSTI-LBNL QA Manager will request DOE/OQA to perform supplier audits.	OSTI-LBNL-QIP-18.0, *Quality Assurance Audits and Management Assessments*
Supplement I, SOFTWARE Software acquisition, development, modification and maintenance shall proceed in a planned, traceable manner utilizing a defined software life cycle methodology. The methodology shall address the	The OSTI-LBNL QA Program has been written to address QA requirements applicable to LBNL.	OSTI-LBNL-QIP-SI.0, *Software Management*

QARD Basic Requirements	Comments/Clarification, Exceptions/Justification	OSTI-LBNL QA Program Implementing Documents (current version)
following phases: requirements, design, implementation, testing, installation and checkout, operations and maintenance, and retirement. The life cycle shall ensure specified points are documented and reviewed. Software verification and validation activities shall be performed and documented for each software, including changes or for systems configurations that are determined to impact the software. Software verification and validation activities shall be performed by individuals not associated with the development of the software, unless justified by higher level of management. A Software Configuration Management (SCM) system shall be established to include configuration identification, configuration change control, and status accounting. A software defect reporting and resolution system shall be implemented for software errors and failures to assure problems are reported to appropriate organizations and to assure resolution.		
Supplement II, SAMPLE CONTROL Samples are to be controlled and identified in a manner consistent with their use. The process for receiving, identifying, handling, analyzing, tracking and storing samples submitted by the Purchaser to the supplier shall be established. Sample traceability shall ensure that the sample can be traced at all times from receipt through final disposition.	The OSTI-LBNL QA Program has been written to address QA requirements applicable to LBNL.	OSTI-LBNL-QIP-SII.0, *Documenting Sample Control*
Supplement III, SCIENTIFIC INVESTIGATION Scientific investigations shall be planned and coordinated with the organization using the results. Scientific investigations shall be performed using implementing documents or scientific notebooks. When technical, or other implementing documents, are not utilized to perform analytical services, scientific investigation activities shall be documented in a scientific notebook that provides a description of the work as planned, methods used to perform work, description of method changes, the results obtained, names of individuals performing work and names of individuals making the entries. Scientific notebooks shall be reviewed by an independent technically qualified individual to verify there is sufficient detail to 1) retrace the investigations and confirm the results, or 2) repeat the investigation and achieve comparable results, without recourse to the original	The OSTI-LBNL QA Program has been written to address QA requirements applicable to LBNL.	OSTI-LBNL-QIP-2.2, *Planning for Science Activities* OSTI-LBNL-QIP-6.1, *Document Review* OSTI-LBNL-QIP-SIII.0, Scientific *Notebooks* OSTI-LBNL-QIP-SIII.1, Technical *Reports* OSTI-LBNL-QIP-SIII.2, Model *Reports* OSTI-LBNL-QIP- SIII.3,

QARD Basic Requirements	Comments/Clarification, Exceptions/Justification	OSTI-LBNL QA Program Implementing Documents (current version)
investigator. Data shall be identified in a manner that facilitates traceability to associated documentation and qualification status for the lifetime of the data. Unqualified data directly relied upon to address safety and waste isolation issues shall be qualified. The qualification process shall be planned and documented. The method for collecting, recording and evaluating data (analytical results) shall be established. Data shall be identified in a manner that provides traceability to samples, associated documentation and computer codes. The method for the conduct of analyses, internal quality control, and/or analytical testing shall be established. Technical reports shall be reviewed and approved in accordance with applicable documents. Model development and approaches to validate shall be planned, controlled, and documented. Planning for model validation shall identify the validation methods and the validation criteria used. If model validation activities will be completed after documentation of the model (for example, using new confirmation test data generated in the field or laboratory), these activities will be described in a Test Plan. Computer software used to develop or execute the model shall be qualified.		*Submittal and Incorporation of Data to the Technical Data Management System* OSTI-LBNL-QIP- SIII.4, *Qualification of Unqualified Data*
Supplement IV, FIELD SURVEYING	Not applicable to current OSTI-LBNL tasks.	N/A
Supplement V, CONTROL OF THE ELECTRONIC MANAGEMENT OF DATA SV applies to the electronic management of data that either exist or are used in an electronic format. This includes data developed as an output of scientific investigation or performance assessment modeling and analysis. The method used to control electronic management of data used as the controlled source for information used in design analysis, process control or scientific investigation shall be described.	The OSTI-LBNL QA Program has been written to address QA requirements applicable to LBNL.	OSTI-LBNL-QIP-SV.0, *Management of OSTI-LBNL-Electronic Data*
Appendix A, HIGH-LEVEL WASTE FORM PRODUCTION	Not applicable to current OSTI-LBNL tasks.	N/A

QARD Basic Requirements	Comments/Clarification, Exceptions/Justification	OSTI-LBNL QA Program Implementing Documents (current version)
Appendix B, STORAGE AND TRANSPORTATION	Not applicable to current OSTI-LBNL tasks.	N/A
Appendix C, MONITORED GEOLOGICAL REPOSITORY		
Modification of QARD Sec 2, QA Program: The use of expert elicitation may be considered if empirical data are not reasonably obtainable, uncertainties are large and significant, more than one conceptual model is permitted by the available data, or technical interpretations are required to properly assess the knowledge and uncertainty in data, processes, and models.	Thus far, expert elicitation has not been scheduled to be used on the OSTI-LBNL Project.	A procedure will be developed should the need for expert elicitation be determined.
Modification to QARD Sec. 4.0, Procurement Document Control, and 7.0, Control of Items and Services: An alternative method for procuring analytical service is developing a quality control sample plan.	Thus far, development of a quality control sample plan has not been scheduled to be used on the OSTI-LBNL Project.	A procedure will be developed should the need for a quality control sample plan be determined.
Modification to QARD Sec. 9, Control of Special Processes, and 10. Inspections	Not applicable to current OSTI-LBNL tasks.	N/A

3. REVISION HISTORY

04/21/04 - Revision 0, Modification 0
Initial issue.

10/08/04 - Revision 0, Modification 1
Deleted specific references to the QARD Revision 14, described QARD requirements in more generic terms.

4. APPROVALS

Prepared by:

(Signature on File) _____ Date _____

Nancy Aden-Gleason
OSTI-LBNL Quality Assurance Manager

Reviewed by:

(Signature on File) _____ Date _____

Yvonne Tsang
OSTI-LBNL Deputy Project Manager

Approved by:

(Signature on File) _____ Date _____

Gudmundur Bodvarsson
OSTI-LBNL Project Manager